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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,992	01/10/2006	Nobuyuki Yoshida	0020-5361PUS1	6388
2292 7590 11/16/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER FRONDA, CHRISTIAN L	
			ART UNIT 1652	PAPER NUMBER
			NOTIFICATION DATE 11/16/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,992	<b>Applicant(s)</b> YOSHIDA ET AL.	
	<b>Examiner</b> Christian L. Fronda	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 6-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4 is/are rejected.
- 7) ☒ Claim(s) 3 and 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/25/07</u> . | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. Claims 1-11 are pending in the application. Claims 6-11 have been previously withdrawn from consideration as being directed toward a non-elected invention.
2. Claims 1-5 are under consideration in this Office Action.
3. The rejection of claims 1-5 under 35 USC 101 as being directed to non-statutory subject matter has been withdrawn in view of applicants' amendment to the claims dated 09/04/2007.
4. The rejection of claims 1 and 4 under 35 U.S.C. 102(b) as being anticipated by Accession AAW69251 (Asahi Kasei Kogyo KK, 28-OCT-1998; reference of record) has been withdrawn in view of applicants' amendment to the claims dated 09/04/2007.

### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claims 1, 2, and 4 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated fructosylamine oxidase comprising the amino acid sequence of SEQ ID NO: 4 or SEQ ID NO: 6; does not reasonably provide enablement for any other embodiment as recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The arguments filed 09/04/2007 have been considered but are not persuasive for reason of record as further explained below.  
Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or

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unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any fructosylamine oxidase of any amino acid sequence for which no structure is apparent since the amended claims recite that the enzyme is from *Fusarium proliferatum*. The recitation of the biological source of the enzyme does not limit the claim to any particular amino acid sequence and structure of the claimed enzyme.

The specification provides guidance and working examples for an isolated fructosylamine oxidase consisting of the amino acid sequence of SEQ ID NO: 4 or SEQ ID NO: 6. However, the specification does not provide guidance, prediction, and working examples for making any fructosylamine oxidase of any amino acid sequence for which no structure is apparent from *Fusarium proliferatum*. Thus, an undue amount of trial and error experimentation must be preformed where such experimentation involves searching and screening a vast number of biological sources for any fructosylamine oxidase having the recited properties.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific amino acid sequence of the claimed fructosylamine oxidase from *Fusarium proliferatum*. Without such a guidance, the amount of experimentation left to those skilled in the art to make the invention is undue and well outside of routine experimentation.

7. Claim 1, 2, and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The arguments filed 09/04/2007 have been considered but are not persuasive for reason of record as further explained below.

The claims are genus claims drawn to a genus of fructosylamine oxidase of any amino acid sequence for which no structure is apparent. The recitation of the biological source of the enzyme does not limit the claim to any particular amino acid sequence and structure of the claimed enzyme. The scope of the genus includes many members with widely differing structural, chemical, and physiochemical properties including widely differing amino acid sequences, structures, and/or biological functions. Furthermore, the genus is highly variable because a significant number of structural and biological differences between genus members exist.

The specification discloses an isolated fructosylamine oxidase consisting of the amino acid sequence of SEQ ID NO: 4 or SEQ ID NO: 6. However, the specification does not describe and define any structural features, amino acid sequences, and/or biological functions that are commonly possessed by members of the genus. The specification fails to provide a written description of representative fructosylamine oxidase other than the fructosylamine oxidase

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consisting of the amino acid sequence of SEQ ID NO: 4 or SEQ ID NO: 6. Thus, one skilled in the art cannot predict and visualize or recognize the identity of the members of the genus.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definitions, such as the structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe the genus of genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g. structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. Therefore, the instant claims are not adequately described.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of the claimed genus of fructosylamine oxidase of any amino acid sequence for which no structure is apparent.

### ***Conclusion***

8. No claim is allowed.

9. Claims 3 and 5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF



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